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1 UNITED STATES PATENT AND TRADEMARK OFFICE

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5 BEFORE THE BOARD OF PATENT APPEALS
6 AND INTERFERENCES

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9 *Ex parte* DENNIS SUNGA FERNANDEZ

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1 The Appellant invented a way to enable secure bioinformatics based
2 transactions, in which on-line service is provided according to a voluntarily
3 submitted genetic profile (Specification 3:3-9).

4 An understanding of the invention can be derived from a reading of exemplary
5 claim 1, which is reproduced below [bracketed matter and some paragraphing
6 added].

7 1. Automated transaction method comprising the steps of:
8 [1] determining electronically
9 a bioinformatic value associated with a user; and
10 [2] transacting via a processor with the user according to the
11 bioinformatic value,
12 wherein the bioinformatic value is automatically determined
13 when or after the user permits access to a voluntarily-
14 selected portion of his or her personal genetic nucleotide
15 profile,
16 such accessible portion being
17 associated or
18 used with
19 evaluating the user transaction via said
20 processor,
21 an other portion of such genetic profile being not
22 voluntarily-selected by the user and thereby inaccessible
23 for evaluating the user transaction.

24
25 This appeal arises from the Examiner's Final Rejection, mailed March 14,
26 2003. The Appellant filed an Appeal Brief in support of the appeal on June 19,
27 2003. An Examiner's Answer to the Appeal Brief was mailed on March 9, 2004.
28 A Reply Brief was filed on May 10, 2004.

1 PRIOR ART

2 The Examiner relies upon the following prior art:

Beecham	US 5,876,926	Mar. 2, 1999
O'Flaherty	US 6,275,824 B1	Aug. 14, 2001
Hoffman	US 6,366,682 B1	Apr. 2, 2002
Rigault	US 6,389,428 B1	May 14, 2002

3 We also discuss the following art in this Decision:

Holden	US 6,640,211 B1	Oct. 28, 2003
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4 Asch, "Genetic Tests: Evolving Policy Questions," IEEE Technology and
5 Science Magazine, Winter 1996/1997, pp. 4-10 (1996).

6 REJECTIONS

7 Claims 1, 5, 7, 8, 11, 12, 21-25, and 27 stand rejected under 35 U.S.C. § 103(a)
8as unpatentable over Hoffman and O'Flaherty.

9 Claims 2-4, 6, 9, 10, and 28 stand rejected under 35 U.S.C. § 103(a) as
10unpatentable over Hoffman, O'Flaherty, and Beecham.

11 Claim 26 stands rejected under 35 U.S.C. § 103(a) as unpatentable over
12Hoffman, O'Flaherty, Beecham, and Rigault.

ISSUES

The issues pertinent to this appeal are

- Whether the Appellant has sustained its burden of showing that the Examiner erred in rejecting claims 1, 5, 7, 8, 11, 12, 21-25, and 27 under 35 U.S.C. § 103(a) as unpatentable over Hoffman and O'Flaherty.
- Whether the Appellant has sustained its burden of showing that the Examiner erred in rejecting claims 2-4, 6, 9, 10, and 28 under 35 U.S.C. § 103(a) as unpatentable over Hoffman, O'Flaherty, and Beecham.
- Whether the Appellant has sustained its burden of showing that the Examiner erred in rejecting claim 26 under 35 U.S.C. § 103(a) as unpatentable over Hoffman, O'Flaherty, Beecham, and Rigault.

The pertinent issue turns on whether it would have been obvious to use a personal genetic nucleotide profile as bioinformatics data in Hoffman.

FACTS PERTINENT TO THE ISSUES

The following enumerated Findings of Fact (FF) are believed to be supported by a preponderance of the evidence.

Facts Related to Claim Construction

1. The disclosure contains no lexicographic definition of “transaction.”
2. The ordinary and customary meaning of “transaction” is the act of transacting, i.e. conducting business.¹

Hoffman

3. Hoffman is directed to tokenless (i.e. without the use of a physical object, such as a credit card) authorization of commercial transactions between a buyer and a seller using a computer system. The buyer registers with the computer system a PIN, at least one registration biometric sample, and at least one buyer financial account. In a proposal step, a seller offers a proposed commercial transaction to the buyer. If the buyer accepts the seller's proposal, in an acceptance step, the buyer signals his/her acceptance by adding to the proposed commercial transaction the buyer's personal authentication information comprising a PIN and at least one bid biometric sample which is obtained from the buyer's person (Hoffman 4:18-33).

¹⁰¹ *American Heritage Dictionary of the English Language* (4th ed. 2000).

4. Hoffman accepts biometric data electronically with a scanner. The biometric scanner can be any one of fingerprint scanner, voice input device (microphone), palm print scanner, retinal scanner or the like (Hoffman 9:27-34).

5. Hoffman's biometric sample and PIN form personal authentication information in its transaction message (Hoffman 21:12-15).

O'Flaherty

6. O'Flaherty is directed to a database management system wherein the data in the database tables is controllably accessible according to privacy parameters stored in the database table. O'Flaherty stores privacy parameters collectively in database columns, and provides access to the data in the database table to a requesting entity solely in accordance with the personal privacy parameters (O'Flaherty 2:57 – 3:11).

7. O'Flaherty masks data that is unauthorized (O'Flaherty 8:16-24).

Facts Related To The Level Of Skill In The Art

8. Neither the Examiner nor the Appellant has addressed the level of ordinary skill in the pertinent arts of tracking items and data formatting. We will therefore consider the cited prior art as representative of the level of ordinary skill in the art. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (“[T]he absence of specific findings on the level of skill in the art does not give rise to reversible error ‘where the prior art itself reflects an appropriate level and a need for testimony is not shown’”) (quoting *Litton Indus. Prods., Inc. v. Solid State Sys. Corp.*, 755 F.2d 158, 163 (Fed. Cir. 1985).

PRINCIPLES OF LAW

2Claim Construction

3 During examination of a patent application, pending claims are given
4their broadest reasonable construction consistent with the specification. *In*
5*re Prater*, 415 F.2d 1393, 1404-05 (CCPA 1969); *In re Am. Acad. of Sci.*
6*Tech Ctr.*, 367 F.3d 1359, 1364, (Fed. Cir. 2004).

7 Limitations appearing in the specification but not recited in the claim are not
8read into the claim. *E-Pass Techs., Inc. v. 3Com Corp.*, 343 F.3d 1364, 1369 (Fed.
9Cir. 2003) (claims must be interpreted “in view of the specification” without
10importing limitations from the specification into the claims unnecessarily).

11 Although a patent applicant is entitled to be his or her own lexicographer of
12patent claim terms, in *ex parte* prosecution it must be within limits. *In re Corr*,
13347 F.2d 578, 580 (CCPA 1965). The applicant must do so by placing such
14definitions in the Specification with sufficient clarity to provide a person of
15ordinary skill in the art with clear and precise notice of the meaning that is to be
16construed. *See also In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994) (although
17an inventor is free to define the specific terms used to describe the invention, this
18must be done with reasonable clarity, deliberateness, and precision; where an
19inventor chooses to give terms uncommon meanings, the inventor must set out any
20uncommon definition in some manner within the patent disclosure so as to give
21one of ordinary skill in the art notice of the change).

22 Obviousness

23 A claimed invention is unpatentable if the differences between it and the
24prior art are “such that the subject matter as a whole would have been obvious at
25the time the invention was made to a person having ordinary skill in the art.”

135 U.S.C. § 103(a) (2000); *KSR Int'l v. Teleflex Inc.*, 127 S.Ct. 1727 (2007);
2 *Graham v. John Deere Co.*, 383 U.S. 1, 13-14 (1966).

3 In *Graham*, the Court held that the obviousness analysis is bottomed on
4 several basic factual inquiries: “[(1)] the scope and content of the prior art are to be
5 determined; [(2)] differences between the prior art and the claims at issue are to be
6 ascertained; and [(3)] the level of ordinary skill in the pertinent art resolved.” 383
7 U.S. at 17. *See also KSR Int'l v. Teleflex Inc.*, 127 S.Ct. at 1734. “The
8 combination of familiar elements according to known methods is likely to be
9 obvious when it does no more than yield predictable results.” *KSR*, 127 S.Ct. at
10 1739.

11 “When a work is available in one field of endeavor, design incentives and
12 other market forces can prompt variations of it, either in the same field or in a
13 different one. If a person of ordinary skill in the art can implement a predictable
14 variation, § 103 likely bars its patentability.” *Id.* at 1740.

15 “For the same reason, if a technique has been used to improve one device,
16 and a person of ordinary skill in the art would recognize that it would improve
17 similar devices in the same way, using the technique is obvious unless its actual
18 application is beyond his or her skill.” *Id.*

19 “Under the correct analysis, any need or problem known in the field of
20 endeavor at the time of invention and addressed by the patent can provide a reason
21 for combining the elements in the manner claimed.” *Id.* at 1742.

ANALYSIS

Claims 1, 5, 7, 8, 11, 12, 21-25, and 27 rejected under 35 U.S.C. § 103(a) as unpatentable over Hoffman and O'Flaherty.

The Appellant argue these claims as a group.

Accordingly, we select claim 1 as representative of the group.
637 C.F.R. § 41.37(c)(1)(vii) (2007).

The Examiner found that Hoffman described all the limitations of claim 1 except for a personal genetic nucleotide profile and having a selectable portion be voluntarily accessible and another portion inaccessible. The Examiner found that a nucleotide profile was simply a long PIN (personal identification number) and that O'Flaherty described a system allowing a user to selectively make portions of data accessible. (Answer 4-5).

The Appellant contends that Hoffman provides no suggestion for using a personal genetic nucleotide profile (Br. 9) and further, that in the absence of such a suggestion, there would be no reason to apply O'Flaherty (Br. 12).

The Examiner responded by taking official notice that a personal genetic nucleotide profile is biometric data and Hoffman accesses biometric data (Answer 1821:Top ¶). The Examiner cites several additional references as evidence that a nucleotide profile may be biometric data in support. The Appellant in turn responds that these references are not of record and more critically, do not suggest the use of such nucleotide data for transactions (Reply Br. 2:First and second full ¶s).

We agree. While the Examiner is correct that Hoffman accepts bioinformatic data for transactions (FF), Hoffman relies upon a scanner that measures observable physical characteristics, such as fingerprints, voice prints, palm prints,

1and retinal patterns (FF). While it is undoubtedly true that a personal genetic
2nucleotide profile is biometric data, this alone is insufficient to find that Hoffman
3would have used such a profile, since a scanner as described by Hoffman could not
4obtain a genetic nucleotide profile.

5 This is hardly surprising, because Hoffman is clearly directed to authentication
6of a user, not analyzing a user's genetic DNA. Hoffman uses its biometric sample
7and PIN to form personal authentication information in its transaction message (FF
8). Thus, Hoffman acquires biometric information that identifies who is actually at
9the scanning device to ensure that person is properly authenticated. Claim 1 recites
10the limitation of relying on a nucleotide profile to complete a transaction. There is
11no requirement that the profile be from a person presently at an input device, nor
12any requirement for authenticating that the profile actually is the user's, although
13the claim requires that the profile actually be the user's. There is simply no way
14for Hoffman's scanner to produce such a profile, and such a profile would be
15useless to Hoffman's authentication mechanism. Thus, we find the Examiner erred
16in rejecting claim 1 over Hoffman and O'Flaherty. Since independent claim 27
17and the remaining dependent claims incorporate this limitation of a personal
18genetic nucleotide profile, we find the Examiner has similarly erred in rejecting
19those claims.

20 The Appellant has sustained its burden of showing that the Examiner erred in
21rejecting claims 1, 5, 7, 8, 11, 12, 21-25, and 27 under 35 U.S.C. § 103(a) as
22unpatentable over Hoffman and O'Flaherty.

1 *Claims 2-4, 6, 9, 10, and 28 rejected under 35 U.S.C. § 103(a) as unpatentable*
2 *over Hoffman, O'Flaherty, and Beecham.*

3 These claims similarly incorporate the limitation of a personal genetic
4 nucleotide profile, and we find the Examiner has erred in rejecting these claims for
5 the same reasons we cited, *supra*.

6 The Appellant has sustained its burden of showing that the Examiner erred in
7 rejecting claims 2-4, 6, 9, 10, and 28 under 35 U.S.C. § 103(a) as unpatentable
8 over Hoffman, O'Flaherty, and Beecham.

9 *Claim 26 rejected under 35 U.S.C. § 103(a) as unpatentable over Hoffman,*
10 *O'Flaherty, Beecham, and Rigault.*

11 This claim similarly incorporates the limitation of a personal genetic nucleotide
12 profile, and we find the Examiner has erred in rejecting this claim for the same
13 reasons we cited, *supra*.

14 The Appellant has sustained its burden of showing that the Examiner erred in
15 rejecting claim 26 under 35 U.S.C. § 103(a) as unpatentable over Hoffman,
16 O'Flaherty, Beecham, and Rigault.

17 CONCLUSIONS OF LAW

18 The Appellant has sustained its burden of showing that the Examiner erred in
19 rejecting claims 1-12 and 21-28 under 35 U.S.C. § 103(a) as unpatentable over the
20 cited prior art.

NEW GROUND OF REJECTION

The following new grounds of rejection are entered pursuant to 337 C.F.R. § 41.50(b).

Independent claims 1, 27, and 28 are rejected under 35 U.S.C. § 102(e) as anticipated by Holden. Dependent claims 10-12, 21, and 23-26 are rejected under 35 U.S.C. § 103(a) as unpatentable over Holden. Claims 2-4, 6-9, and 22 are rejected under 35 U.S.C. § 103(a) as unpatentable over Holden and Asch. Claim 5 is rejected under 35 U.S.C. § 103(a) as unpatentable over Holden and O'Flaherty.

ADDITIONAL FACTS PERTINENT TO THE ISSUES

The following additional enumerated Findings of Fact (FF) are believed to be supported by a preponderance of the evidence.

Holden

9. Holden is directed to storing and accessing genetic information and providing protection against unauthorized access and use, but providing convenience in accessing and using genetic information if such use is properly authorized (Holden 1:23-27).

10. Holden's patient enrolls in a genetic banking system for multiple patients and provides a source of genetic material, such as a blood sample. The sample is processed to produce a genetic profile for the patient. The processed data is stored in a database to create a genetic profile for that patient (Holden 1:28-35).

11. The patient, either at the time of enrollment or after a sample is processed, can dictate access rights, including the ability of third parties (other than the individual or the genetic bank itself), such as medical

practitioners, to access this profile, and the specific purposes for which the profile can be accessed and used. Thus, the patient can specify both the people who will have access, and the uses for which they have access (Holden 1:36-43).

12.A medical practitioner authorized to have access by the patient and confirmed by the access control system can access the profile and perform a transaction such as running tests based on the profile (Holden 1:49-54).

13.Holden's system allows users to store a comprehensive digitized DNA profile based on a sample. The patient has control to voluntarily allow access to particular people and for particular purposes, thus protecting the privacy of that information (Holden 1:63-67).

14.Holden's system may include data integration and analysis functionalities (Holden 2:19-21).

15.Holden describes the use of a server in a separate system for data access (Holden 2:39-48).

16.Some of Holden's authorized third parties may have access for some purposes and not for other purposes (Holden 2:60-65).

17.Holden derives its profiles by the genetic banking and testing services that are provided, and can include genotyping and bioinformatic profiling of general and/or specific genetic marker panels. Such information can be used to determine risks of many diseases including, without limitation, cancer, Huntington's Disease, Alzheimer's Disease, and hypertension. The data that is provided from these tests is digitally

1 stored in the database as a genetic profile of the patient for subsequent
2 analysis and tests (Holden 3:31-47).

3 18.If access is allowed, Holden's practitioner can seek to have a test
4 performed, such as a search of the profile for markers for Huntington's
5 Disease. The system determines whether the test is authorized by
6 comparing the type of test that is desired with the access rights entered
7 by the patient (a practitioner may have access for some purposes but not
8 others). If the test is authorized, the processing system forwards the
9 request to the testing system to perform the test (Holden 3:66 – 4:6).

10 19.Holden's system allows a patient to voluntarily bank genetic information
11 that can be used quickly to determine genetic and medical information
12 about that individual, particularly information that relates to whether the
13 individual carries genetic information associated with known diseases.
14 The system provides restrictions, however, that allow the user to retain
15 privacy and limit unauthorized access to his/her genetic information.
16 The system is thus unlike a system, for example, in which DNA
17 information, like fingerprint information, is stored for identification
18 purposes to use DNA information to identify individuals involved in
19 specific criminal activities; in such a case, the individual who provides
20 the sample would generally not have voluntary control to establish the
21 ability of others to access the information, and such systems would
22 generally not have the ability to test for a number of different medical
23 purposes for which the DNA information can be accessed by others
24 (Holden 5:62 – 6:12).

1 *Asch*

2 20. Asch is directed to exploring policy questions surrounding genetic
3 testing (Asch 4:Title).

4 21. A 1991 survey of insurers found that most health insurers believe it is
5 fair for insurers to use genetic tests to identify individuals with increased
6 risk of disease, and that they should have the option of determining how
7 to use genetic information in determining risks. One reason insurers
8 might use such tests is that individuals can undergo genetic testing on
9 their own, and if they discover that they are at greater medical risk they
10 might purchase more insurance. This phenomenon, known as adverse
11 selection, puts insurance companies at a disadvantage if they lack access
12 to the same information. To level the playing field, insurance companies
13 might have a legitimate interest in the results of genetic tests already
14 performed, and might have an incentive to initiate testing for selected
15 conditions. When one insurer begins to use genetic information in its
16 risk rating, others must follow or they will disproportionately attract
17 individuals who are denied coverage elsewhere. This suggests that
18 insurance companies will inevitably begin to use genetic information in
19 risk rating, despite the expense and complexities involved. Some
20 analysts have argued that this inexorable trend contradicts the rationale
21 for insurance in the first place (Asch 9:Left col. Third full ¶ - Right col.
22 First full ¶).

1

ANALYSIS

2 The anticipation of claims 1, 27, and 28 by Holden is demonstrated in the
3 following chart.

<u>Claim 1</u>	<u>Holden</u>
1. Automated transaction method comprising the steps of: [1] determining electronically a bioinformatic value associated with a user; and [2] transacting via a processor with the user according to the bioinformatic value, wherein the bioinformatic value is automatically determined when or after the user permits access to a voluntarily-selected portion of his or her personal genetic nucleotide profile,	Running tests based on the stored profile (Holden 1:49-54) Same as above - basing on profile shows the determination, running tests shows the transaction Patient voluntarily allows access for particular people and purposes (Holden 1:63-67) -- genotyping and bioinformatic profiling of genetic marker panel (Holden 3:34-39); nucleotide polymorphism map (Holden 4:38-42)
such accessible portion being associated or used with evaluating the user transaction via said processor, an other portion of such genetic profile being not voluntarily-selected by the user and thereby inaccessible for evaluating the user transaction. The party processing the transaction being a caregiver (Claim 28)	Running tests based on the stored profile (Holden 1:49-54) A practitioner may access for some purposes but not others (Holden 4:1-5) The party is a medical practitioner (Holden 1:36-43)

4 All of the limitations of claims 27 and 28 form a subset of the limitations of
5 claim 1, except the claim 28 limitation of a caregiver, which is also included in the
6 chart.

1 As to claims 10-12, 21, and 23-26, rejected as obvious over Holden, we find as
2 follows.

- 3 • Holden describes a server for storing data and remote transactions (FF)
4 (claim 10).
- 5 • A portable computer is a predictable variation of Holden's computer and
6 patient control over data implies a patient identification, which is sufficient
7 to create a patient account (claim 12).
- 8 • Holden describes multiple patients (FF) (claim 11).
- 9 • Holden describes a remote system (FF), which implies origination and
10 transmission of a data as a signal (claims 21 and 25).
- 11 • Holden describes data analysis functionality (FF). Analysis testing for data
12 that is clearly incorrect (claim 23) or comparing differences between similar
13 data (claim 24) are known by those in the art of data analysis to be
14 predictable variations of data analysis in general, and indeed are frequently
15 considered "sanity check" type testing to determine anomalies. The
16 combination of familiar elements according to known methods is likely to be
17 obvious when it does no more than yield predictable results. *KSR*, 127 S. Ct.
18 at 1739.
- 19 • The DNA profiles of Holden clearly have correspondence with at least a
20 single nucleotide polymorphism (claim 26).

1 As to claims 2-4, 6-9, and 22, rejected over Holden and Asch, we find as
2 follows.

- 3 • Asch describes the use of genetic profile information as requisites for
4 insurance policies (FF). Claim 2 requires such an insurance policy, and
5 claims 3 and 4 require a service contract or bid to serve, each of which a
6 health insurance policy would represent.
- 7 • Asch describes the lack of precision in predicting actual circumstances,
8 implying the actuarial table of claim 6, and the applicability to group
9 insurance and the policy questions regarding discrimination, implying the
10 non-discrimination of claim 7.
- 11 • Claims 8 and 9 recite multiple values from the bioinformatic data, which the
12 various tests described by Holden would require, and such data also
13 indicating a change in risk, which Holden's examples describe.
- 14 • Claim 22 requires competitive transactions and insurance transactions are
15 known to be competitive.
- 16 • One of ordinary skill would have considered the transactional considerations
17 of Asch after considering Holden because of Asch's description of the
18 commercial policy implications of the technology employed by Holden, and
19 found it obvious to combine their teachings.

20 As to claim 5, rejected over Holden and O'Flaherty, O'Flaherty describes the
21 use of masking to accomplish data hiding (FF &). One of ordinary skill would
22 have seen this as an implementation technique for Holden's denial of access to
23 some portions of data (FF) and found it obvious combine them by employing
24 O'Flaherty for its implementation details.

DECISION

To summarize, our decision is as follows:

- The rejection of claims 1, 5, 7, 8, 11, 12, 21-25, and 27 under 35 U.S.C. § 103(a) as unpatentable over Hoffman and O'Flaherty is not sustained.
- The rejection of claims 2-4, 6, 9, 10, and 28 under 35 U.S.C. § 103(a) as unpatentable over Hoffman, O'Flaherty, and Beecham is not sustained.
- The rejection of claim 26 under 35 U.S.C. § 103(a) as unpatentable over Hoffman, O'Flaherty, Beecham, and Rigault is not sustained.
- The following new grounds of rejection are entered pursuant to 37 C.F.R. § 41.50(b).
 - Independent claims 1, 27, and 28 are rejected under 35 U.S.C. § 102(e) as anticipated by Holden.
 - Claims 10-12, 21, and 23-26 are rejected under 35 U.S.C. § 103(a) as unpatentable over Holden.
 - Claims 2-4, 6-9, and 22 are rejected under 35 U.S.C. § 103(a) as unpatentable over Holden and Asch.
 - Claim 5 is rejected under 35 U.S.C. § 103(a) as unpatentable over Holden and O'Flaherty.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv).

REVERSED

41.50(b)

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